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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/841,609	04/25/2001	Vitaliy Arkadyevich Livshits	206339US0	4787	
38108	7590 06/03/2004		EXAM	EXAMINER	
	O CORPORATE SER UAL PROPERTY DEPA	KERR, KATHLEEN M			
1120 CONNECTICUT AVE., N.W.			ART UNIT	PAPER NUMBER	
WASHINGTON, DC 20036			1652		
			DATE MAILED: 06/03/200	4	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	09/841,609	LIVSHITS ET AL.				
Office Action Summary	Examiner	Art Unit				
	Kathleen M Kerr	1652				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address						
Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠ Responsive to communication(s) filed on <u>01 April 2004</u> .						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) Claim(s) 4,7 and 8 is/are pending in the application.						
4a) Of the above claim(s) 8 is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6) Claim(s) <u>4 and 7</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers		-				
9)☐ The specification is objected to by the Examiner.						
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> </ul>						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary (	(PTO-413)				
Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)     Paper No(s)/Mail Date	Paper No(s)/Mail Dai					

U.S. Patent and Trademark Office PTOL-326 (Rev. 1-04)

Art Unit: 1652

#### **DETAILED ACTION**

Page 2

### **Application Status**

1. In response to the previous Office action, an Advisory action (mailed on March 10, 2004), Applicants filed a request for continued examination (RCE) with a request to enter the previously filed amendment (received February 25, 2004). Said amendment cancelled Claim 1-3, 6, and 9-12 and amended Claims 4, 7, and 8. Thus, Claims 4, 7 and 8 are pending in the instant Office action.

#### Election

2. Claims 4, 7, and 8 are pending in the instant application. Claim 8 is withdrawn from further consideration as non-elected inventions. Claims 4 and 7 will be examined herein.

#### **Priority**

3. As previously noted, the instant application is granted the benefit of priority for the foreign application 2000110350 filed on April 26, 2000 in Russia. No translation of the priority document has been received.

#### Withdrawn - Claim Rejections - 35 U.S.C. § 112

- 4. Previous rejection of Claims 6 and 9-12 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "csc genes" is withdrawn by virtue of Applicant's cancellation of said claims.
- 5. Previous rejection of Claims 6 and 9-12 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicant's cancellation of said claims.

Application/Control Number: 09/841,609 Page 3

Art Unit: 1652

6. Previous rejection of Claims 6 and 9-12 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicant's cancellation of said claims.

#### Maintained - Claim Rejections - 35 U.S.C. § 112

7. Previous rejection of Claims 4 and 7 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "sucrose non-PTS genes" is maintained and altered since the phrase added via amendment, "csc genes originating from Escherichia coli", is also not clear for the same reasons. Moreover, this term was previously rejected as being found confusing in Claims 9-12. Applicant is urged to respond to the following issues as taken from the previous rejection of Claims 9-12:

"The term 'csc genes' is unclear. On page 7, the specification notes that csc genes can be obtained from *E. coli* EC3132; however, it is unclear if this is the only source. If not, then what are the criteria of being a csc gene? If one looks to the art for definition, again the claims are unclear. Sahin-Toth *et al.* (as supplied by Applicants) describe a sucrose-hydrolase invertase gene 98% identical to cscA of Bockmann *et al.* (see pages 418-419); however, no related permease and fructokinase genes are noted. Must an entire regulon be used or can one piecemeal a regulon together from known genes? If piecemeal is acceptable, then, again, one of skill in the art must be able to identify a csc permease or a csc fructokinase that can work together with a csc invertase".

Applicant's arguments have been fully considered but are not deemed persuasive. Applicant argues that the amendment has clarified the claim, but this is not the case as noted above.

Clarification is required so that the metes and bounds of the instant claims can be determined.

8. Previous rejection of Claims 4 and 7 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive. Applicants argue that the amendment obviates the rejection; the Examiner

Art Unit: 1652

disagrees, particularly since Claim 10 had been so rejected and the limitations of Claim 10 have been incorporated into Claim 4.

Applicant is urged to respond to the following issues, wherein as previously noted, Sahin-Toth *et al.* describes an example of a csc gene that is a sucrose-hydrolase invertase from *E. coli*. Thus, the only csc gene described other than that of Bockmann *et al.* as noted in the specification, is a single invertase gene of a function more specifically denoted than described in the specification. This limited description in the specification and the art does not adequately describe the claimed genus. Thus, in view of the specification and the art, one of skill in the art would be unable to predict the structure of the genes in the genus claimed.

9. Previous rejection of Claims 4 and 7 under 35 U.S.C. § 112, first paragraph, scope of enablement, is maintained. Applicant presents no arguments specific to the enablement rejection other than the amendment has obviated the rejection. The Examiner disagrees. Applicant is urged to respond to the issue wherein, as previously noted, "the ability to ---find--- does not satisfy the ability to "make" as required by the statute."

### Withdrawn - Claim Rejections - 35 U.S.C. § 102

10. Previous rejection of Claims 6 and 9-12 under 35 U.S.C. § 102(b) as being anticipated by Bockmann *et al.* is withdrawn by virtue of Applicant's cancellation of said claims.

## Maintained - Claim Rejections - 35 U.S.C. § 102

11. Previous rejection of Claims 4 and 7 under 35 U.S.C. § 102(b) as being anticipated by Bockmann *et al.* is maintained. Applicant's arguments have been fully considered but are not

Art Unit: 1652

deemed persuasive for the following reasons. Applicant argues that the limitation of producing amino acids in an amount higher that in bacteria non harboring esc genes is not taught by Bockmann *et al.*; thus, Bockmann *et al.* do not teach all the limitations of the claims. The Examiner disagrees.

Bockmann *et al.* teach *E. coli* JM109 harboring the expression plasmid pJMBL102, which contains the csc genes (see page 27, right column). Absent evidence to the contrary, such a transformant inherently accumulates amino acids in the media, as previously noted.

Additionally, the Examiner notes that Applicant's own examples evidence this fact. On page 29, Table 4, *E. coli* strain 44-3-15 absent any csc-gene-containing plasmid produces isoleucine and on page 35, Table 7 *E. coli* strain SV164 absent any csc-gene-containing plasmid produces tryptophan.

Moreover, absent evidence to the contrary, the mere introduction of csc genes increases amino acid production in *E. coli*. Again, the Examiner notes that Applicant's own examples evidence this fact. On page 29, Table 4, the mere introduction of csc genes into *E. coli* strain 44-3-15 produces an increase of isoleucine production of 0.1% (see glucose numbers; no limitation to amino acid production on sucrose is in the claims).

Thus, Bockmann *et al.* inherently teach the product claimed with all its limitations since said limitations are an inherent feature of the product explicitly taught by Bockmann *et al.* In fact, if this inherency is not the case, the instant claims are lacking an essential element that would produce such functionality.

Art Unit: 1652

### Summary of Pending Issues

- 12. The following is a summary of the issues pending in the instant application:
  - a) Claims 4 and 7 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "csc genes originating from Escherichia coli".
  - b) Claims 4 and 7 stand under 35 U.S.C. § 112, first paragraph, written description.
  - c) Claims 4 and 7 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.
  - d) Claims 4 and 7 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Bockmann *et al*.

#### Conclusion

13. Claims 4 and 7 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kathleen M Kerr

Sath Lok-

Examiner

Art Unit 1652